REMARKS

Claims 1-14 and 44-70 are pending in this application for the Examiner's review and consideration. Claims 15-43 were canceled in response to a Restriction Requirement.

THE REJECTIONS UNDER 35 U.S.C. § 103(A)

The Rejection of Claim 1 as Being Obvious Over U.S. Patent No. 5,719,197 to Kanios *et al.*

Claim 1 was rejected under 35 U.S.C. § 103(a) as being obvious over U.S. patent no. 5,719,197 to Kanios *et al.* ("Kanios") for the reasons set forth on pages 2-3 of the Office Action. Specifically, the Examiner alleges that Kanios discloses a composition comprising a solvent, an active agent, and a carrier and that the solvents include fatty acids such as linoleic acid, the active agent can be fluoxetine, and that 2-hexyl decanoic acid is a lipophilic counterion. Therefore, the Examiner alleges it would have been obvious to employ fluoxetine, decanoic acid, and linoleic acid in a composition.

Applicant further notes that the Office Action states at page 3, under the heading titled "Claim Rejections - 35 USC § 103" that "Claims and 2-14, 45-54, and 56-57 are rejected as being indefinite to the extent that they read on a rejected base claim." Applicants are unclear what is meant by the claims being "indefinite" when the rejection is based on 35 USC § 103. Applicant does note, however, that if claims 2-14, 45-54, and 56-57 are being rejected 35 USC § 103 as obvious over Kanios, **this is a new ground for rejection that was not previously made and is not being made in response to claim amendments. Accordingly, the finality of the Office Action should be withdrawn.** For the purposes of this Amendment, Applicants assume that this is a new rejection and that the finality of the present Office Action will be withdrawn.

As the Examiner is aware, in order to render claims obvious under 35 U.S.C. § 103(a), the prior art must disclose or suggest every limitation of the claimed invention and provide the person of skill in the art with a reasonable expectation that the invention will work for its intended purpose. *KSR International Co. v. Teleflex Inc. et al.*, 127 S. Ct. 1727 at 1739-41 (2007).

Kanios does not disclose each and every feature of the invention recited in claim 1,

suggest the invention, or provide a reasonable expectation of success. Without limitation as to other deficiencies in Kanios, the reference does not, at a minimum, disclose or suggest a composition that is "for oral administration or an injectable composition." Rather, Kanios discloses compositions that are for topical administration. The compositions disclosed in Kanios are not described as being suitable for oral administration or administration by injection. The requirements for a composition for topical administration are completely different from those for a composition for oral administration or administration by injection. For example, compositions for topical administration, unlike compositions for oral administration or administration by injection, must be able to adhere to the skin or mucosa (*See*, Kanios, column 4, lines 62 to column 5, lines 5 and column 6, lines 23-27). Indeed, the compositions disclosed in Kanios include excipients, such as clays and bioadhesives, which allow the compositions to adhere to the skin and mucosa, that would not be suitable for inclusion in a composition for oral administration or administration by injection. Indeed, such compositions, because of the bioadhesive, are sticky and, therefore, could not be drawn into a syringe (*i.e.*, an "injectable composition, " *see*, specification, ¶ [0019]) or administered orally. Formulations for oral administration must be adequately absorbed when ingested and injectable formulations must be taken up into the system without causing undue tissue damage. Kanios is silent regarding these differences. There is simply no disclosure or suggestion in Kanios of a composition for oral administration or administration by injection or that the topical compositions disclosed therein could be modified so as to be suitable for oral administration or administration by injection. Moreover, even if Kanios did suggest that the formulations disclosed therein could be formulated for oral administration or administration by injection, which it does not, the reference does not provide the requisite reasonable expectation that such a composition, if formulated for oral administration or administration by injection, would successfully release the active compound over time.

Applicant notes that the Examiner states that

> a recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

(*See*, Office Action, page 8). The recitation in claim 1 "to form a composition for oral

administration or an injectable composition" is not an intended use but a characteristic of the claimed composition (they can be drawn into a syringe and injected or administered orally, *i.e.*, swallowed), characteristics that clearly distinguish the claimed composition from the compositions disclosed in Kanios (*i.e.*, adhesive topical compositions). Defining a part of an invention by functional language is permitted (Manual of Patent Examining Procedure ("MPEP") ¶ 2173.05(g)). "Functional language does not, in and of itself, render a claim improper" (MPEP ¶ 2173.05(g), citing *In re Swinehart*, 439 F.2d, 210, (CCPA 1971)) and "the limitation used to define a radical on a chemical compound as 'incapable of forming a dye with said oxidizing developing agent' although functional, was perfectly acceptable because it set definite boundaries on the patent protection sought" (MPEP ¶ 2173.05(g), citing *In re Barr*, 444 F.2d 588 (CCPA 1971)). As discussed above, a composition "for oral administration or an injectable composition" will be formulated in a completely different way from a composition, such as described in Kanios, that is intended for topical application.

The Examiner further asserts that the claim language *comprising* leaves the claim open for unspecified ingredients, even in major amounts and as such, does not exclude the excipients recited in Kanios" (*See*, Office Action, page 8). Applicants respectfully traverse. The claim clearly recites "to form a composition for oral administration or an injectable composition." Thus, although the claim uses the transitional phrase "comprising," it precludes components that would render the composition unsuitable for oral administration or administration by injection, such as those required for a composition intended for topical administration, such as disclosed in Kanios.

The Examiner further asserts that

> oral administration of an agent does not limit the formulation to those ingredients that are ingested. Oral administration would include administration of agents that are applied to the buccal cavity, and as such would require bioadhesives to adhere to the mucosal surface of the buccal cavity, such as bioadhesives and clay.

Applicant respectfully disagrees. One of ordinary skill in the art would readily understand that "oral administration" to be different from applying agents to the buccal cavity, *i.e.*, buccal administration. Oral administration means administration by swallowing and release and absorption of the drug in the gastrointestinal tract. In contrast, buccal administration is a type of

topical administration and, like all topical administration, involves administering the drug by transferring the drug across a mucosal membrane. Specifically, in the case of buccal administration, across the mucosal membrane of the buccal cavity. Oral administration and topical administration are different. For example, topical administration, unlike oral administration, by-passes metabolism by the liver. That buccal administration is understood to be a form of topical administration is evidenced by *Goodman & Gillmans The Pharmacological Basis of Therapeutics*, 9th ed. McGraw Hill (1996), page 8 (Goodman's," attached hereto as Exhibit A), which clearly recognizes buccal administration as a form of topical administration. Indeed, the '197 patent also recognizes that transfer across the buccal mucosa is considered topical administration, not oral administration (*See*, the '197 patent, column 1, lines 48-57). Moreover, *Remington: The Science and Practice of Pharmacy,* 20th ed., University of the Sciences in Philadelphia, p. 1142-1143 ("Remington," attached hereto as Exhibit A) clearly recognizes oral administration as distinct from buccal administration. The recitation in claim 1 "to form a composition for oral administration or an injectable composition" clearly distinguishes the claimed composition from that disclosed in Kanios and, as discussed above, there is absolutely no recognition in Kanios of a composition for oral administration or administration by injection or that the topical compositions disclosed therein could be modified so as to be suitable for oral administration or administration by injection.

The rejection of claim 1 as being obvious over Kanios is the impermissible use of hindsight to reconstruct Applicants' invention. The Examiner has used Applicants' invention as a blueprint to combine selected parts of Kanios, when there is no motivation to do so, to arrive at Applicants' invention. It is well settled that hindsight cannot be used to reject a claim as obvious. *In re Sernaker,* 702 F.2d 989, 994 (Fed. Cir. 1983); *In re Rinehart, 531* F.2d 1048 (CCPA 1976); *In re Imperato,* 486 F.2d 585 (CCPA 1973); *In re Adams,* 356 F.2d 998 (CCPA 1966); *In re Anita Dembiczak,* 75 F.3d 994, 999 (Fed. Cir. 1999); *C.R. Bard Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998) citing *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 (Fed. Cir. 1985) (holding the prior art must suggest to one of ordinary skill in the art the desirability of the claimed combination).

For example, the Examiner cites Kanios as disclosing linoleic acid as a water immiscible solvent. Linoleic acid, however, is selected from a long list of useful solvents, most of which are

water miscible (*See*, Kanios, column 4, lines 3-11). There is, however, no disclosure or suggestion to select a solvent that is a water immiscible solvent, as required by claim 1.

Similarly, the Examiner selects fluoxetine from a laundry list of pharmacologically active compounds that spans more than 19 columns of the patent. There is, however, no disclosure or suggestion to select a pharmacologically active compound that is capable of forming a salt with a lipophilic counterion. The Examiner then selects 2-hexyldecanoic acid from the same laundry list of pharmacologically active compounds disclosed in Kanios as disclosing a lipophilic counterion. Kanios merely discloses that fluoxetine and 2-hexyldecanoic acid are pharmacologically active compounds that can be used in the topical compositions disclosed therein. There is, however, no suggestion or motivation provided in Kanios to combine a lipohilic counterion (such as 2-hexyldecanoic acid) with a pharmacologically active compound (such as fluoxetine) to provide a salt, much less that the resulting salt should be combined with a water immiscible solvent, to form a composition for oral administration or an injectable composition. The Examiner is clearly picking and choosing selected disclosures of Kanios, using Applicants' specification as guideline, to arrive at Applicants' invention. Applicants respectfully submit that Kanios can only be construed to render claim 1 obvious by the impermissible use of hindsight reconstruction.

For the reasons set forth above, Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. § 103(a) as being obvious over Kanios be reconsidered and withdrawn.

The Rejection of Claims 1, 44, 45-48, 50, 51, 54, and 55-13 Under 35 U.S.C. § 103(a) as Being Obvious Over U.S. Patent No. 7,011,846 to Shojaei *et al.*

Claims 1, 44, 45-48, 50, 51, 54, and 55 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. patent no. 7,011,846 ("Shojaei") for the reasons set forth on pages 3-4 of the Office Action. Specifically, the Examiner alleges that Shojaei teaches a composition for oral administration comprising an active compound such as fluoxetine, a lipophilic counterion (decanoic acid), and a water immiscible solvent (castor oil). Applicants respectfully traverse.

Shojaei discloses an oral capsule containing non-aqueous solubilizers with increased physical stability (*See*, Shojaei, column 1, lines 41-43). According to Shojaei non-aqueous solubilizers can adversely effect capsule integrity (*Id.* at column 1, lines 14-34). By including a

capsule stabilizing agent, stability of the capsule is improved (*Id.* at column 1, lines 49-54). Capsule stabilizing agents include fatty esters of glycerol, fatty esters of polyethylene glycol, fatty esters of propylene glycol, fatty acids, and mixtures thereof (*Id.* at column 2, lines 11-14). Shojaei simply describes a method for stabilizing capsules.

Shojaei does not disclose each and every feature of the invention recited in independent claims 1 and 44, suggest the invention, or provide a reasonable expectation of success. Shojaei simply discloses various components can minimize decomposition of a capsule from exposure to a non-aqueous solubilizer such as 2-pyrrolidone and N-C_{1-4} alkylpyrrolidones. There is, however, no disclosure to form a salt between a pharmacologically active compound and a lipophilic counterion or to combine the resulting salt with a water immiscible solvent. The Examiner asserts that Shojaei discloses fluoxetine as a pharmacologically active compound. Fluoxetine, however, is simply included in Shojaei as part of a long laundry list of active compounds (*Id.* at column 4, line 66 to column 7, line 28). The extensive and lengthy list of pharmaceutically active compound in Shojaei, however, provides absolutely no motivation or suggestion to select a pharmaceutically active compound that can form a salt with a lipophilic counterion. The Examiner then cites Table 1 of Shojaei as disclosing decanoic acid as a lipophilic counterion. Table 1, however, merely shows that decanoic acid is a suitable stabilizer for N-methyl-2-pyrrolidone ("NMP"). There mere disclosure in Shojaei that decanoic acid can minimize capsule decomposition in the presence of NMP, however, provides no motivation or suggestion to combine the stabilizer with a pharmaceutically active compound that can form a salt. There is absolutely no disclosure or suggestion in Shojaei that would motivate one of ordinary skill in the art to select, from the laundry list of pharmacologically active compounds disclosed therein, a pharmacologically active compound that can form a salt with a lipophilic counterion, to form a salt between the pharmacologically active compound and a lipophilic counterion, and to then combine the resulting salt with a water immiscible solvent. Indeed, there is no disclosure in Shojaei of using a water immiscible solvent.

The Examiner also asserts that Table 1 of Shojaei discloses castor oil as a water immiscible solvent. The capsules used in Table 1, however, are filled with NMP (*Id.* at column 8, line 56 to column 9, line 1), which is a water *miscible* solvent (not water immiscible, as required by claim 1). The castor oil is merely used as a stabilizing agent. Moreover, Table 1

shows that castor oil is *not* a suitable stabilizer for NMP. Thus, if anything, Shojaei teaches away from using castor oil.

Moreover, even if Shojaei did provide the requisite motivation, which it does not for the reasons stated above, the reference provides no reasonable expectation that such a composition would be effective as a composition for oral administration or an injectable composition that releases the active compound over time when administered to a mammal, as recited in independent claims 1 and 44. Applicants respectfully submit that the rejection of the claims as obvious over Shojaei is again the impermissible use of hindsight in an attempt to reconstruct Applicants' invention. The Examiner is selectively picking and choosing various parts of the broad disclosure of Shojaei, without any motivation to do so, other than by using Applicants' specification as guideline, to arrive at Applicants' invention. As discussed above, such hindsight reconstruction is impermissible.

The Examiner states at page 10 of the Office Action that

> It is not clear to the Examiner what picking and choosing is needed in order to determine what medicaments are specifically described in Shojaei to determine which agents are hydrophobic. All that is needed to implement the disclosure of Shojaei is to combine any hydrophobic agent recited (the patent is drawn to a formulation of a hydrophobic pharmaceutically active agents in a solubilizing composition) with the water immiscible solvents along with decanoic acid.

(*See*, Office Action, page 10). The issue is not what is needed to implement Shojaei. The issue is what is need to arrive at the *claimed invention* in view of Shojaei. As discussed above, to arrive at Applicants' invention, one must first select a pharmacologically active compound that can form a salt with a lipophilic counterion, one must then select a lipohilic counterion that can form a salt with the active compound, and then combine the two so as to form a salt. Shojaei, directed to stabilizing capsules, provides no suggestion motivation in to do this. Nor is there any motivation or suggestion to formulate such a salt with a water immiscible solvent. The Examiner has used Applicants specification as a road map to pick and choose selected disclosures from Shojaei, a completely unrelated reference directed to stabilizing capsule, to arrive at Applicants invention without any motivation to do so.

For the reasons set forth above, Applicants respectfully request that the rejection of claims 1, 44, 45-48, 50, 51, 54, and 55-13 under 35 U.S.C. § 103(a) as being obvious over

Shojaei be reconsidered and withdrawn.

The Rejection of Claims 1-5, 11, 12, 44, 45-48, 50, 51, 54, 55, 58-61, 67, and 68 Under 35 U.S.C. § 103(a) as Being Obvious Over U.S. Patent No. 6,174,540 to Williams *et al.*

Claims 1-5, 11, 12, 44, 45-48, 50, 51, 54, 55, 58-61, 67, and 68 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. patent no. 6,174,540 ("Williams") for the reasons set forth on pages 4-5 of the Office Action. Specifically, the Examiner alleges that Williams teaches an injectable formulation comprising an active agent, such as an antibiotic, and a water immiscible solvent, hydrogenated castor oil, and capric acid. Applicants respectfully traverse.

Williams discloses a long acting injectable formulation that includes a therapeutic agent, hydrogenated castor oil, and a hydrophobic carrier (*See*, Williams, column 3, lines 46-59).

Williams, however, like Shojaei, does not disclose each and every feature of the invention recited in independent claims 1 and 44. Specifically, contrary to the Examiner's assertions, Williams does not disclose or suggest a lipophilic counterion. The Examiner asserts that the abstract discloses a formulation that includes capric acid. The abstract, however, does *not* disclose a formulation that includes capric acid. Rather, the abstract discloses "propyl dicaprylates/dicaprates, caprylic/capric acid triglycerides," which are *esters* of caprylic acid and capric acid. Being *esters* of caprylic acid and capric acid, rather than the free acid, they are not capable of forming a salt with a pharmacologically active compound and, thus, are not a lipophilic counterion.

The Examiner goes on to state that

> applicant asserts that the capric acid disclosed is capric acid triglyceride, which are esters of caprylic acid and capric acid, not capable of forming a salt with a pharmacologically active compound. However, **there is nothing in the claim that limits the lipophilic counterion to form a salt with the pharmacologically active compound**. The claim recites a composition comprising a salt of the pharmacologically active compound with a water miscible solvent. The lipophilic counterion can be an ionized form of a C_1-C_{22} saturated or unsaturated fatty acid.

(*See*, Office Action, pages 10-11, emphasis added). The above statement that "there is nothing in the claim that limits the lipophilic counterion to form a salt with the pharmacologically active compound" makes no sense. Independent claims 1 and 44 clearly state "a salt of the

pharmacologically active compound with a lipophilic counterion." Such a statement makes Applicants wonder how carefully the Examiner has read and considered the claims and the prior art. Applicants agree with the Examiner that "[t]he lipophilic counterion can be an ionized form of a C_1-C_{22} saturated or unsaturated fatty acid." This is exactly the reason why Williams does not render the claims obvious. The lipophilic counterion must be charged, for example, by donating a proton. The specification clearly states

> By a "lipophilic counterion" is meant an ionized form of a fat soluble molecule. The lipophilic counterion may be an ionized form of a fatty acid, but may also be another fat soluble molecule. The counterion has at least one charge opposite to that of a chemical group on an opposing salt member, thereby causing an ionic attraction between the two molecules.

(*See*, specification, ¶ [0013]). Williams, by disclosing *esters* of caprylic acid and capric acid, discloses compounds that cannot donate a proton. Therefore, the compounds disclosed in Williams *cannot* form a charged species that is required to form a salt (*See*, specification, ¶ [0012]). Being *esters* of caprylic acid and capric acid, rather than the free acid, the compounds disclosed in Williams are not capable of forming a salt with a pharmacologically active compound and, thus, are not a lipophilic counterion. Accordingly, there is no disclosure or suggestion in Williams of a salt formed between a pharmacologically active compound and a lipophilic counterion, much less to combine this salt with a water immiscible solvent.

Moreover, there is nothing in Williams that would motivate one of ordinary skill in the art to form a salt between a pharmacologically active compound and a lipophilic counterion and to then combine the resulting salt with a water immiscible solvent.

For the reasons set forth above, Applicants respectfully request that the rejection of claims 1-5, 11, 12, 44, 45-48, 50, 51, 54, 55, 58-61, 67, and 68 under 35 U.S.C. § 103(a) as being obvious over Williams be reconsidered and withdrawn.

The Rejection of Claims 1-8,11,12, 14, 44-51, 54, 55, 57-64, 67, 68, and 70 Under 35 U.S.C. § 103(a) as Being Obvious Over U.S. Patent No. 6,309,663 to Patel *et al.*

Claims 1-5, 11, 12, 44, 45-48, 50, 51, 54, 55, 58-61, 67, and 68 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. patent no. 6,309,663 ("Patel") for the reasons set forth on page 5-6 of the Office Action. Specifically, the Examiner asserts that Patel discloses a

pharmaceutical composition for oral or parenteral use comprising an active agent, such as gentamycin or fluoxetine that is combined with a hydrophobic surfactant (water immiscible solvent), such as castor oil, palm kernel oil, and corn oil, and ionizable surfactants that are in their ionized form, such as oleic acid, capric acid, linoleic acid, and lauric acid. Applicants respectfully traverse.

Patel discloses a triglyceride free pharmaceutical system having a dosage form of an absorption enhancing composition comprising at least two surfactants, at least one of which is hydrophilic, and a hydrophobic therapeutic agent (*See*, Patel, column 4, lines 1-5).

Similar to the other references, Patel does not disclose each and every feature of the invention recited in independent claims 1 and 44, suggest the invention, or provide a reasonable expectation of success. Patel discloses an absorption enhancing formulation. Patel, however, does not disclose or suggest forming a salt between a pharmacologically active compound and a lipophilic counterion or to combine the resulting salt with a water immiscible solvent. The Examiner asserts that Patel discloses gentamycin and fluoxetine as a pharmacologically active compound. Each of these compounds, however, is simply included as part of a long laundry list of active compounds (*Id.* at column 29, line 41 to column 32, line 18). Similarly, the Examiner asserts that Patel discloses ionizable surfactants that are in their ionized form, such as oleic acid, capric acid, linoleic acid, and lauric acid. Again, the disclosure of these surfactants is part of a long laundry list of surfactants spanning over 10 pages of the patent (*Id.* at column 6, line 55 to column 29 line 5). There is, however, no disclosure or suggestion in Patel that would motivate one of ordinary skill in the art to select, from the long laundry list of active compounds recited therein, a pharmacologically active compound that can form a salt with a lipophilic counterion or to select, from the long laundry list of surfactants disclosed therein, a surfactant that is a lipophilic counterion, to then form a salt between the pharmacologically active compound and the lipophilic counterion, and then combine the resulting salt with a water immiscible solvent. Moreover, Patel provides no reasonable expectation that such a composition would successfully release the active compound over time.

In response to the argument that surfactants are part of a laundry list of active compounds, the Examiner states that

> when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. *Ex Parte A*, 17 USPQ 2d 1716 (Bd. Pat. App. & Int. 1990) (The claimed compounds was named in a reference which also disclosed 45 other compounds. The Board held that the comprehensiveness of the listing did not negate the fact the compound claimed was specifically taught.
>
> * * *
>
> In the instant case, the species is hydrophilic agents in which simple dissolution is not sufficient to provide efficient absorption of the therapeutic agent.

(*See*, Office Action, pages 11-12). The above matter is completely different from that in *Ex Parte A*. In *Ex Parte A* Applicant was trying to claim a single compound that was named within a list of compounds in the prior art. Applicants claimed compositions do not involve simply claiming a composition that is recited in a list. Rather, Applicants discovery is a composition made by forming a salt of a pharmaceutically active compound and a lipophilic counterion and combining the salt with a pharmaceutically acceptable water immiscible solvent to form a composition that is suitable for oral administration or an injectable composition that releases the active compound over time when administered to an animal (claim 1) or is a clear solution (claim 44). Unlike the matter in *Ex Parte A*, Applicants composition is not a species that has been selected from a list of species in Patel. Patel does not disclose, much less even suggest, the composition claimed in independent claims 1 and 44. Patel merely discloses that using surfactants can enhance absorption of hydrophilic therapeutic agents using various absorption-enhancing componetns (*See*, Patel, column 3, line 51-53 and column 4, line 46-60). The present matter is clearly distinguished from that in *Ex Parte A*.

Applicant again notes that the Examiner states that "it is noted that the features upon which applicant relies (i.e., **forming a salt between a pharmacologically active compound and a lipophilic counterion**) are **not** recited in the claims(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims" (*See*, Office Action, page 11, emphasis added). Applicants are not arguing that limitations from the specification should be read into the claims. Rather, as noted above, independent claims 1 and 44 clearly and unambiguously recite "a **salt** of the pharmacologically active compound with a lipophilic counterion" (emphasis added). The claims clearly recite a "salt." Applicants respectfully submit that a careful and thorough reading of the claims and prior would clearly show that the prior art does not render the claims obvious.

Moreover, and importantly, Patel, by disclosing a "an absorption enhancing composition" (*See*, Patel, column 4, lines 1-5 and column 45, lines 51-58) *teaches away* from the invention claimed in independent claim 1 that recites a "composition that releases the active compound over time when administered to the mammal." Patel, by teaching away from a feature required in independent claim 1, clearly cannot render independent claim and claims dependent therefrom obvious.

Again, Applicants respectfully submit that the Examiner's rejection of the claims is the impermissible use of hindsight in an attempt to reconstruct Applicants' invention. The Examiner is selectively picking and choosing various parts of the broad disclosure of Patel, absent a motivation to do so, to reconstruct Applicants' invention. As discussed above, such hindsight reconstruction is impermissible.

The Examiner, however, states

> it is not clear what picking and choosing is needed in order to determine what medicaments are specifically described in Patel et al. to determine which agents are included as part of the invention. *All that is needed to implement the disclosure of Patel et al.* is to combine any of the agents recited [ ] with the water immiscible solvents recited along with decanoic acid. There does not appear to be any difficulty in arriving at the decision.

(*See*, Office Action, page 12, emphasis added). The issue is not what "*is needed to implement the disclosure of Patel et al.*" The issue is what is need to implement the *claimed invention* in view of Patel. As discussed above, to arrive at Applicants' invention, one must first select a pharmacologically active compound that can form a salt with a lipophilic counterion from the long laundry list of active compounds recited in Patel (many of which do not form a salt), must then select a surfactant that is a lipophilic counterion from the long list of surfactants disclosed in Patel (many of which are not lipophilic salts), must then form a salt between the pharmacologically active compound and the lipophilic counterion, and then combine the resulting salt with a water immiscible solvent. Again, Patel is a vast disclosure and there is no motivation or suggestion to select the combination of components required to arrive at Applicants invention. The Examiner has used Applicants specification as a road map to pick and choose selected disclosures in Patel to arrive at Applicants invention without any motivation to do so and, in fact, with a teaching away from Applicants' invention.

For the reasons set forth above, Applicants respectfully request that the rejection of claims 1-8,11,12, 14, 44-51, 54, 55, 57-64, 67, 68, and 70 under 35 U.S.C. § 103(a) as being obvious over Patel be reconsidered and withdrawn.

DOUBLE PATENTING

Claims 1-14 and 44-70 were provisionally rejected on the grounds of non-statutory obviousness-type double patenting as being unpatentable over claims 65-138 of co-pending application serial no. 11/088,922 ("the '992 application") for the reasons set forth on pages 6-8 of the Office Action. Specifically, the Examiner alleges that claims of the present application are not patentably distinct from the claims of the '992 application because the instant and conflicting claims recite substantially the same subject matter differing only in the description of the particular components claimed.

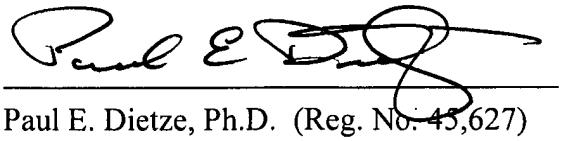
Applicants note that the rejection is provisional. Accordingly, once all rejections of the claims over prior art have been addressed, Applicants will submit a Terminal Disclaimer disclaiming the term of any patent that should issue from the above-identified application that would extend beyond the term of the '992 application.

CONCLUSIONS

It is respectfully submitted that all claims are now in condition for allowance, early notice of which would be appreciated. Should the Examiner disagree, Applicants respectfully request a telephonic or in-person interview with the undersigned attorney to discuss any remaining issues and to expedite eventual allowance of the claims.

No fee is believed to be due for this submission. Should any additional fees be required, please charge the required fees to Kenyon & Kenyon deposit account no. 11-0600.

Respectfully submitted,



Date: December 19, 2007

Paul E. Dietze, Ph.D. (Reg. No. 45,627)

KENYON & KENYON
1500 K Street, NW
Washington, D.C. 20005-1257
(202) 220-4200-p
(202) 220-4201-f
Customer No.: 2383